



DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

(B-46-2013)

Foreign-Trade Zone (FTZ) 61 – San Juan, Puerto Rico
Notification of Proposed Production Activity
Janssen Ortho LLC
(Pharmaceutical Products Production)
Gurabo, Puerto Rico

The Puerto Rico Trade and Export Company, grantee of FTZ 61, submitted a notification of proposed production activity to the FTZ Board on behalf of Janssen Ortho LLC (Janssen), located in Gurabo, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on April 29, 2013.

A separate application for subzone status at the Janssen facility was submitted and will be processed under Section 400.31 of the FTZ Board's regulations. The facility is used for the production of various prescription and over-the-counter pharmaceutical products. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products listed in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Janssen from customs duty payments on the foreign status components used in export production. On its domestic sales, Janssen would be able to choose the duty rates during customs entry procedures that apply to various prescription and over-the-counter pharmaceutical products, including: anti-cancer; anti-diabetic and immunosuppressive medicaments; analgesics; antipyretic and anti-inflammatory agents; and, cough and cold preparations (duty free) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: splenda sucralose; cobicistate silicon dioxide; metformin; canagliflozin; and darunavir ethanolate API (duty rates range from 86.2 cents/kg to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is ***[insert date 40 days from date of publication]***.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230-0002, and in the "Reading Room" section of the FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Diane Finver at Diane.Finver@trade.gov or (202) 482-1367.

Dated: May 16, 2013

Andrew McGilvray
Executive Secretary